UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,312	11/13/2001	Leroy E. Hood	P - IS 4988	5632

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EXAMINER
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ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

	Application No.	Applicant(s)
Office Action Summary	09/993,312	HOOD ET AL.
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *27 September 2005*.
2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-74* is/are pending in the application.
    4a) Of the above claim(s) *34 and 44-74* is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) *1-33 and 35-43* is/are rejected.
7) ☒ Claim(s) *3* is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on *13 November 2001* is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a) ☐ All   b) ☐ Some * c) ☐ None of:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____.
      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) ☐ Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in

37 CFR 1.17(e), was filed in this application after final rejection. Since this application is

eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e)

has been timely paid, the finality of the previous Office action has been withdrawn pursuant to

37 CFR 1.114. Applicants' submission, filed 9/27/05, has been entered.

Amended claims 1, 16, and 32, filed 9/27/05, are acknowledged.

Claims herein under examination are 1-33 and 35-43. Claims 34 and 44-74 are

withdrawn as being drawn to a non-elected species and non-elected Groups.

Claim Objection

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for

failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of
matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions
and requirements of this title.

Claims 1-33 and 35-43 are rejected under 35 U.S.C. 101 because these claims are

directed to non-statutory subject matter.

Claims 1-33 and 35-43 are directed to methods of predicting a behavior of a biochemical

system comprising a series of mathematical steps for data manipulation, equivalent to mental

processes. Applicant is reminded that mental processes are not statutory subject matter under 35

USC 101.

As set forth in MPEP 2106.IV.B.I:

If the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals
representing any of the foregoing, the acts are not being applied to appropriate subject matter.
Schrader, 22 F.3d at 294-95, 30 USPQ2d at 1458-59. Thus, a process consisting solely of
mathematical operations, i.e., converting one set of numbers into another set of numbers, does
not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application (i.e.,
executing a "mathematical algorithm"); or

- simply manipulate abstract ideas, e.g., a bid (*Schrader*, 22 F.3d at 293-94, 30 USPQ2d at 1458-
59) or a bubble hierarchy (*Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759), without some
claimed practical application.

The methods of claims 1-33 and 35-43 are not restricted to be computer-implemented

methods; however, the specification indicates that the methods are intended to be implemented

by a computer. In the event that the claimed method steps are implemented by a computer, the

method claims are not statutory due to a lack of physical transformation outside the computer

and a practical application (as discussed below).

According to MPEP 2106.IV.B.2(b):

To be statutory, a claimed computer-related process must either: (A) result in a physical transformation
outside the computer for which a practical application in the technological arts is either disclosed in the
specification or would have been known to a skilled artisan, or (B) be limited to a practical application
within the technological arts. See *Diamond v. Diehr*, 450 U.S. at 183-84, 209 USPQ at 6 (quoting
Cochrane v. Deener, 94 U.S. 780, 787-88 (1877)).

As set forth in MPEP 2106.IV.B.2(b)(i), two "safe harbors" considered to satisfy the

"physical transformation outside the computer" requirement include the following:

(1) A process is statutory if it requires physical acts to be performed outside the computer independent of and following the steps to be performed by a programmed computer, where those acts involve the manipulation of tangible physical objects and result in the object having a different physical attribute or structure. *Diamond v. Diehr*, 450 U.S. at 187, 209 USPQ at 8.

(2) Another statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data (*In re Gelnovatch*, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979).

No physical acts or measurement of physical objects or activities are recited in claims 1-

33 and 35-43. Therefore, these claims fail to recite anything considered to be a physical

transformation as explained above.

As discussed in MPEP 2106.IV.B.2(b)(i):

If a claim does not clearly fall into one or both of the safe harbors, the claim may still be statutory if it is limited to a practical application in the technological arts.

As set forth in MPEP 2106.IV.B.2(b)(ii), an explanation of "practical application" as well

as some examples of claimed inventions that have a practical application include the following:

A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See *AT&T*, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557 (*>en< banc*). For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory.

The "practical application" toward which instant claims 1-33 and 35-43 are apparently

directed is predicting a behavior of a biochemical system. This "practical application" does not

satisfy the 35 USC 101 statutory requirements, because there is no concrete, tangible, *and* useful

result in these claims. For example, the correlative changes that predict such a behavior are not available to the user in a tangible form in the instant claims.

Because the claimed methods merely recite steps of mathematically manipulating data and fail to recite a physical transformation (as explained above) or produce a practical application (a concrete, tangible, and useful result), claims 1-33 and 35-43 do not recite statutory subject matter.

Applicants argue that the claimed invention is directed to statutory subject matter. This statement is found unpersuasive as the claimed methods merely recite steps of mathematically manipulating data and fail to recite a physical transformation (as explained above) or produce a practical application (a concrete, tangible, and useful result). Applicants argue that instant claims 1, 16, and 32 have been amended to clearly specify that the claimed method of predicting a behavior of a biochemical system includes producing a comparison of data integration maps and that the identified correlative changes predict a behavior of the biochemical system which is indicative of a changing condition. It is noted that "producing a comparison" can be interpreted to take place within the computer without any physical act or measurement of physical objects or activities. This interpretation lacks a physical transformation outside the computer (one way to satisfy statutory requirements under 35 USC 101). It is further noted that identifying correlative changes that predict a behavior does not provide a tangible result (i.e. output or display) for a user. A practical application that qualifies a claimed invention as statutory subject matter must produce a concrete, tangible, *and* useful result.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the phrase "said value sets further comprise at least two or more data elements" which is confusing as to its intended meaning. One interpretation of this limitation is that "said value sets" is referring to the value sets as a whole which would mean that the two value sets would only need one data element each. This contradicts the limitations of instant claim 1 wherein each value set contains two or more different types of data elements. Another interpretation of this limitation is that "said value sets" is referring to the value sets individually such that each value set of the two value sets requires at least two data elements resulting in a minimum of four data elements (two data elements for each of the at least two value sets). Clarification of the intended meaning of this phrase via clearer claim wording is requested.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-33 and 35-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Rine et al. (P/N 5,777,888).

Rine et al. disclose analyzing stimulus-response patterns of a living thing using deduction protocols applied through artificial intelligence systems such as expert systems and neural networks (abstract) which represents predicting the behavior of a biochemical system, as stated in instant claims 1, 16, and 32. Rine et al. disclose performing comparisons to deduce the mechanism of action and characteristics of the responsible stimulus (col. 5, lines 37-49) which represents a prediction of cell behavior (of a biochemical system) indicative of a changing condition, as stated in claims 1, 16, and 32. Rine et al. disclose constructing a stimulated physical matrix (data integration map which is a physical interaction map), detecting a physical signal (value) at each unit of the physical matrix and storing the data with X and Y coordinates of the corresponding physical matrix unit and stimulus, and repeating this procedure to form a database (col. 2, lines 4-15). Rine et al. disclose using various conditions/perturbations, including pharmaceutical agent stimuli, suspected pathogenic agents, and radiative energy (col. 3, lines 48-51) which represent two or more different perturbed conditions, as stated instant claims 1, 7, 16, 22, 32, and 36. The term "network" is broadly defined in several ways in the instant specification (page 10, line 26 to page 11, line 32) that includes a group of interacting molecules in two or more pathways and have common function in a biochemical function. A "network" is also defined as containing one or more components involved in a biochemical function which could be interpreted to be a cell, nucleic acid, or countless other cellular

component parts. Thus, two cells involved in each microarray as discussed by Rine et al. would

qualify as two independent networks, as stated in instant claims 1, 2, 16, 17, 32, and 33. Rine et

al. disclose using a microtiter plate with 96 wells with a cell or colony of cells in each well (col.

10, lines 38-41) which represent at least 96 networks, as stated in instant claims 6, 21, and 35.

Rine et al. disclose comparing an output signal matrix to an output signal matrix database

(containing other matrices) for correlating candidate stimuli and responses (abstract and col. 1,

line 66 to col. 2, line 3 and col. 2, lines 25-29) which represents identifying correlative changes

predicting a behavior indicative of a changing condition, as stated in instant claims 1, 16, and 32.

Rine et al. disclose performing comparisons to generate correlates and qualitative and/or

quantitative deduction analyses (col. 5, lines 56-63 and Figure 5) which represents producing a

comparison of two or more data integration maps and identifying correlative changes in at least

two value sets, as stated in instant claims 1, 16, and 32. Rine et al. disclose using an array

containing a different responder of a living thing in each unit which may comprise an organism's

entire repertoire of responders including genes, gene regulatory elements, gene transcripts

(mRNA) or translates (proteins), or a predetermined functional class or subset of the organism's

entire repertoire as well as a sufficient ensemble of responders to deduce the action of a stimulus

(col. 2, lines 30-44) which represent at least three different types of data elements within value

sets (as stated in instant claims 1, 3, 4, 16, 18, 19) and at least five components (as stated in

instant claims 14, 29, and 41). Rine et al. disclose measuring gene expression levels in cells (col.

4, lines 11-17) and using various conditions/perturbations, including pharmaceutical agent

stimuli, suspected pathogenic agents, and radiative energy (col. 3, lines 48-51) which represent a

nucleic acid expression data element type and a physical interaction data element, as stated in

instant claims 5, 13, 15, 20, 28, 31, 32, 40, and 43. Rine et al. disclose measuring responses for

each cell in the matrix under a variety of conditions, such as pH, temperature, medium, and

osmolarity (col. 11, lines 21-28) which represents multiple data elements. Rine et al. disclose

measuring cells of the matrix before and after interactions with a pharmacological agent which

might include monitoring as a function of other variables such as stimulus intensity, duration, or

time (col. 4, lines 51-57) which represents repeated measurements on at least two value sets with

three data element types with perturbed conditions for substantially all components within at

least one network (as stated in instant claims 8, 23, and 37) as well as obtaining a first integration

map and producing a second integration map under a perturbed condition, as stated in instant

claims 16 and 32. Values taken during the drug interaction measurements over time as discussed

above in a 96-well microtiter plate represent value sets within the same network (measurements

in the same well) as well as within different networks (measurements in different wells) as stated

in claims 9, 10, 24, and 25. Rine et al. disclose a system for creating physical matrices, storing

the matrices in a database, and a comparison function (col. 3, lines 9-19) as well as repeating the

process of creating response profiles for compounds 2 through N (any number, i.e. 3) (col. 11,

lines 30-40) which represents data integration maps comprising changes in three or more value

sets, as stated in instant claims 11, 26, and 38. Rine et al. disclose similarities in a shared

response pathway in sterol biosynthesis between human cells and yeast cells resulting increased

expression levels but in different nucleic acids when exposed to drug Mevacor (col. 6, lines 14-

28). Rine et al. disclose using a microtiter plate to test an inhibitor on various strains of yeast

which varies in no expression, increased expression, or decreased expression depending on the

strains (col. 6, lines 44-54) which represents inversely coordinated changes in nucleic acid

expression data elements, as stated in claims 12, 27, and 39. Rine et al. disclose measuring cells of the matrix before and after interactions (col. 4, lines 51-57) as well as constructing a stimulated physical matrix, detecting physical signals, storing the data, and iteratively storing signal matrix data for a plurality of stimuli to form a matrix database (col. 2, lines 4-15) which represents repeating steps at least once under a different perturbed condition, as stated in instant claims 30 and 42. Rine et al. disclose comparing a response profile to a reference profile and repeating the process for compounds or mixtures of compounds 2 through N (col. 11, lines 29-40). Rine et al. disclose using this procedure in testing drug administration (perturbation and physical interaction) to identify compounds with a particular biological effect (col. 1, lines 40-57). Rine et al. disclose steps to generate various response profiles (including value sets) for known and unknown stimuli (col. 2, lines 60-64). Rine et al. disclose using a wide variety of stimuli and adjusting incubation conditions to preclude cellular stress (col. 3, lines 59-63). Thus, Rine et al. anticipate the instant invention.

Applicants summarize the Rine et al. rejection. Applicants state that they have amended the claims to recite that each data integration map includes two or more value sets containing two or more different types of data elements. The "two or more different types of data elements" limitation is addressed in the rejection above.
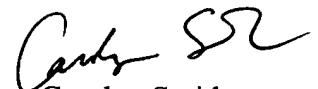
Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile

transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The

faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30

(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)

(See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-

8300.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The

examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be

directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-

0549.

December 6, 2005

Carolyn Smith
Examiner
Art Unit 1631